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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 6300  
SEATTLE, WA 98104-7092

EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/088,282

Applicant(s)

KRIPPNER ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-17 and 19-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-17 and 19-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/15/2002.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

*Ne*

### DETAILED ACTION

Applicants' response, which included cancellation of claim 14, 18 and amendment to claims 1, 4, 6, 7, 9, 12, 15-17, 19-22, 29, 30 and 32 filed on 7/13/2005, is made of record. Claims 1-13, 15-17 and 19-33 are now pending.

In view of applicants; response the following rejections apply.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15-17 and 19-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim and shares the same indefiniteness.

1. Recitation of "and are functional binding residues of a compound of formula I renders claim 1 indefinite, as it is not clear whether claim 1 embraces compound of formula I or some other compound of undefined structure. Note compound of formula I meets the requirements of two or more capsid binding cores separated by a X-W-Y spacer. It is therefore not clear what other structural elements are included in the "functional binding residues" which are capsid binding moiety not that of compound of formula I.

Furthermore, it is not clear whether the non-polymeric backbone or core is monovalent or divalent and if it is to be attached to compound of formula 1, what

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happens to the functional moiety essential for capsid binding. Hence as recited claim 1 is vague and unclear as to what the invention is and what is precisely claimed.

This reaction is similar to that made in the previous office action. Applicants' amendment did not obviate the rejection but necessitated additional basis for the rejection.

2. Claims 2-5, 7, 9, 11, 12 13, 19, 20, 22 and 23 recite various functional language, which are not given any weight, as a compound is a compound irrespective of its function. A compound is a compound irrespective of its intended use or desirable property. Claims 2-22, 24-26, 30 and 32-33 are compounds claims with some attributes to the compound. These attributes do not change the structure of the compound and make it different from compound of claim 1.

See *Intirtool, LTD. V. Texar Corp.*, 70 USPQ2D 1780. Note court held that " In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art.'"

Instant claims are compound claims and are clearly defined by a structure of formula I. Omission of the attributes to the compound of these claims does not

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alter the structure of these compounds. Hence, claims 2-5, 7, 9, 11, 12 13, 19, 20, 22 and 23 are duplicate claims. Applicants assert that they are not. In which case these claims are vague and unclear as to what is the structural make-up of these claims are and how they further limit compound claim 1 structurally. Note a compound is defined by its structure and these dependent claims should do so to indicate they are further limiting claim 1.

3. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 refers to a "symmetrical dimer" and it is not clear what dimer is being recited. Is it the dimer of formula I or the formula itself to be symmetrical?

Applicants' traversal to obviate this rejection is not persuasive. First of the question is not what is a dimer or what is symmetrical. It is question of what is the structural make-up of the symmetrical dimer is, so that such a limitation is incorporated in a proper search and the claim examined properly. In the instant case there are too many variables. The two aromatic cores and the X-W-Y group and as originally recited something derived from these is to be symmetrical dimer. It is hard to guess what it is. In addition, the amended claim 1 adds additional vagueness. Is a symmetrical dimer now includes the non-polymeric core to be symmetrical? If the non-polymeric backbone or core is monovalent, how can the derived structure be symmetrical dimer?

Hence, this reaction is proper and is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13 and 15-17 and 19-33 are rejected 35 U.S.C 102(b) as being anticipated by Joseph-McCarthy et al., WO 99/29280 (equivalent US 6, 416, 762) or Tsang et al. WO 99/29908.

Joseph-McCarthy et al., teaches several anti-picornaviral compounds for treating picornaviruses infections, which include compounds generically claimed in the instant claims. See entire document especially pages 3-4 and figures 1-4 for formula of compounds made. Joseph- McCarthy et al. teaches in these pages compounds that

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bind to piconavirus capsid comprising two or more capsid binding aromatic cores as seen pages 3-8. Note the compounds disclosed include two optionally substituted aromatic cores connected through X and Y to a divalent spacer groups as required in the instant claims. See pages 8-9 for process of making these compounds and pages 10-12 for examples 1-4 for library of the compounds made. See also figures 1-4 for the same.

Tsang et al. also teaches the same compounds and method of use and method of identifying anti-picornaviral compounds. See entire documents including figures 1A, 3A and 4A for compounds and assay protocol.

Claims 1-13, 15-17 and 19-33 are rejected 35 U.S.C 102(b) as being anticipated by Hogle et al., US 5,637,708.

Hogle et al., teaches several antiviral agents with capsid binding which include compounds generically claimed in the instant claims. See entire document especially formula shown in column 2, lines 29, 42 and 47 as well as Figures 1-24 for various compounds and the process of making them. Note when instant X and Y are absent that is m and n are 0, then compounds taught by Hogle et al. include instant compounds.

Claims 1-13, 15-16 and 19-33 are rejected 35 U.S.C 102(b) as being anticipated by Sato et al., US 4,818,761.

Sato et al., teaches several antiviral agents with capsid binding which include compounds generically claimed in the instant claims. See entire document especially formula shown in column 1, line 40 and formula I in column 2 and note the definition of

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X. Note when instant X or Y is NH and the other absent and W is CH<sub>2</sub>, compounds taught by Sato include instant compounds. See column 3-10 for Table I and II and examples 1-8 for various compounds made.

Claims 1-13, 15-16 and 19-33 are rejected 35 U.S.C 102(b) as being anticipated by Daneshtalab et al., US 5,026,848.

Daneshtalab et al., teaches several antiviral agents with capsid binding which include compounds generically claimed in the instant claims. See entire document especially formula 1 in column 1, line 26 and note the definition of R and R<sup>1</sup>. Note when instant X or Y is O and the other absent and W is (CH<sub>2</sub>)<sub>n</sub>, compounds taught by Daneshtalab include instant compounds. See column 4-15 for examples 1-47 for various compounds made.

Claims 1-13, 15-17 and 19-33 are rejected 35 U.S.C 102(e) as being anticipated by Tian et al. US 6,355,807.

Tian et al., teaches picornaviruses inhibitors, which include compounds generically claimed in the instant claims. See entire document especially formula I in column 3 and formula II in column 12 and note the definition of Z, Z<sub>1</sub>, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub>. Note with the definitions of these groups, the compounds taught by Tian meet the structural requirement of the instant formula I. More specifically, when R<sub>9</sub> is a heterocyclic group (heteroaryl), R<sub>7</sub> and/ or R<sub>8</sub> aryl or heteroaryl, and/or Z, Z<sub>1</sub>, R<sub>1</sub> is a aryl or heteroaryl or form a hetero ring as permitted by Tian et al. and with the side chain bonding these meeting the X-W-Y requirement, the compounds taught by Tian et al.



includes instant compounds. See column 20 through column 26 including Schemes 1-3, for process of making.

All these 102 rejection are same as made in the previous office action but now exclude the cancelled claims 14 and 18.

Applicants have not addressed these rejections fully but have asserted that examiner did not understand the instant invention.

This is not correct.

The rejections are based on factual analysis of originally presented claims and the presently amended claims.

Contrary to applicants' contention, the scope of the instant claims includes prior art compounds. Instant claims require two or more capsid binding moieties, which include functional groups on aromatic ring, attached through a non-[polymeric backbone or core. This requirement is clearly met with in the references cited above.

For example, Tian et al clearly teaches several compounds which have three or more aromatic cores with functional groups linked through non-polymeric backbone. In fact the compounds shown in instant Table 2, 1-30, has the same two or more aromatic core linked through some spacer which applicants, consider as non-polymeric backbone or core.

On the whole, applicants have not defined their invention precisely to exclude the above prior art compounds.

These rejections are proper and are maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 15-17 and 19-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joseph-McCarthy et al., WO 99/29280 (equivalent US 6, 416, 762) or Tsang et al. WO 99/29908.

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Teachings of Joseph-McCarthy et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Joseph-McCarthy et al., teaches several anti-picornaviral compounds for treating picornaviruses infections, which include compounds generically claimed in the instant claims.

Although Joseph-McCarthy permits several five, six and fused five and six-membered heterocyclic rings for the aromatic group and various divalent groups for the spacer groups. See page 6 last paragraph through page 8, Joseph-McCarthy et al., teaches only few examples of the genus embraced in formula of library 1, library 2 and library 3.

However, Joseph-McCarthy et al. teaches equivalency of exemplified compounds with those generically claimed for Library 1, Library 2 and Library of compounds.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds with various aromatic groups linked through various spacers as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

The same applies to Tsang et al., which discloses same compounds as in Joseph-McCarthy.

Claims 1-13, 15-17 and 19-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogle et al., US 5,637,708.

Teachings of Hogle et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Hogle et al., teaches several antiviral agents with capsid binding which include compounds generically claimed in the instant claims.

Although Hogle et al., permits several five, six and fused five and six-membered heterocyclic rings for the group U and W and various divalent groups for the spacer group V as seen in column 4, Hogle et al., teaches only few examples of the genus embraced in formula shown in column 2, lines 29, 42 and 47 as seen in Figures 1-24.

However, Hogle et al. teaches equivalency of exemplified compounds with those generically claimed for formula shown in column 2, lines 29, 42 and 47.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds with various aromatic groups linked through various spacers as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-13, 15-16 and 19-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Sato et al., US 4,818,761.

Teachings of Sato et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Sato et al., teaches several antiviral agents with capsid binding which include compounds generically claimed in the instant claims. See entire document especially formula shown in column 1, line 40 and formula I in column 2.

Sato et al., teaches only few examples of the genus embraced in formula shown in column 1, line 40 and column 2, formula I.

However, Sato et al. teaches equivalency of exemplified compounds with those generically claimed for formula I shown in column 2 or formula in line 40 of column 1.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds with variously substituted in benzimidazole ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-13, 15-16 and 19-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daneshtalab et al., US 5,026,848.

Note when instant X or Y is O and the other absent and W is  $(CH_2)_n$ , compounds taught by Daneshtalab include instant compounds. See column 4-15 for examples 1-47 for various compounds made.

Teachings of Daneshtalab et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Daneshtalab et al., teaches several antiviral agents with capsid binding which include compounds generically claimed in the instant claims. See entire document especially formula 1 in column 1, line 26 and note the definition of R and R<sup>1</sup>.

Although Daneshtalab et al., permits several five, six and fused five and six-membered heterocyclic rings for the group R and R<sup>1</sup>, Daneshtalab et al., teaches only few examples of the genus embraced in formula I shown in column 1, line 26.

However, Daneshtalab et al. teaches equivalency of exemplified compounds with those generically claimed for formula I shown in column 1, line 26.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds with various aromatic groups linked through various spacers as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-13, 15-17 and 19-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tian et al. US 6,355,807.

Teachings of Tian et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Tian et al., teaches picornaviruses inhibitors, which include compounds generically claimed in the instant claims. See entire document especially formula I in column 3 and formula II in column 12 and note the definition of Z, Z<sub>1</sub>, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub>.

Although Tian et al., permits several aryl and heteroaryl groups for R<sub>9</sub>, R<sub>7</sub>, R<sub>8</sub> and Z, Z<sub>1</sub>, R<sub>1</sub>, Tian et al., teaches only few examples of the genus embraced in formula I and formula II.

However, Tian et al. teaches equivalency of exemplified compounds with those generically claimed for formula I and formula II.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds with various aromatic/heteroaromatic groups linked through various spacers as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

These rejections are same as made in the previous office action. These 103 rejections are proper and are maintained for reason already discussed in the above 102 rejections.

***Duplicate claims***

Claims 2-5, 7, 9, 11, 12 13, 19, 20, 22 and 23 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). A compound is a compound irrespective of its intended use or desirable property. Claims 2-5, 7, 9, 11, 12 13, 19, 20, 22 and 23 are compounds claims with some attributes to the compound. These attributes do not change the structure of the compound and make it different from compound of claim 1.

See *Intirtool, LTD. V. Texar Corp.*, 70 USPQ2D 1780. Note court held that “ In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give” life, meaning, and vitality to claim.’.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,’ the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art.”

Instant claims are compound claims and are clearly defined by a structure of formula I. Omission of the attributes to the compound of these claims would not alter the

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structure of these compounds. Hence claims 2-5, 7, 9, 11, 12 13, 19, 20, 22 and 23 are duplicate claims.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Acting Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson whose telephone number is (571) 272-0661.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any inquiry of a general nature or relating to the status of



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this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

*Venkataraman Balasubramanian*  
Venkataraman Balasubramanian

9/29/2005